

Remarks

The pending Office Action has been carefully considered. Eighteen claims remain in this application, numbered 1-3, 5-18 and 21. Claim 1 is the sole independent claim. Claims 1 and 21 have been amended.

The title of this application has been changed to "Ostomy Pouch Adhesives Such As Polysiloxanes That Are Resistant to Stomal Effluent."

The present invention as claimed in independent claim 1 is directed to a two-component ostomy device. The two components are a body attaching wafer component and a pouch component. The body attaching wafer component is adhereable to the body.

The body attaching wafer component and the pouch component are capable of being adhered to each other and are capable of being separated from each other.

The two components are adhereable and separable at a pressure sensitive adhesive interface. They are also positionable on the body to collect stomal fluid. The pressure sensitive adhesive interface includes one or more polysiloxanes, or one or more polysiloxanes and at least one silicate resin including their blend and reaction products. The adhesives interface resists migration of stomal fluids into it and the interface is resealable.

The references cited by the Examiner applied singly or in combination do not anticipate, under 35 U.S.C. 102, or render obvious, under 35 U.S.C. 103, the present invention as presently claimed in amended independent claim 1.

The Examiner cited and applied McNally (U.S. 4,831,070), Wagner (U.S. 6,520,943) and Abber (WO86/00532) in rejecting the formerly pending claims.

As discussed below, none of these references applied singly or in combination teach or suggest a stomal effluent resistant pressure sensitive, resealable polysiloxane adhesive interface between a body attaching wafer component and a pouch component that are adhereable to each other and separable from each other, as presently claimed in amended independent claim 1.

More specifically, McNally is directed to the seal between the stoma on a person's body and a body attaching device. McNally is not concerned with connecting two device components as is the present invention, as presently claimed.

The Examiner states that “McInally discloses a pressure sensitive adhesive polydiorganosiloxane to form a seal between the stoma of an ostomy patient and an attached appliance . . .” Forming a seal between the stoma and an attached appliance does not suggest or teach the two-component adhesive interface between the adhereable and separable body attaching wafer component and pouch component as claimed in amended independent claim 1. The adhesive being described by McInally would be more accurately described as an ostomy seal. McInally is not directed to or concerned with an adhereable and separable two-component system that has a pressure sensitive adhesive interface that is resistant to stomal effluent and is resealable between a body attaching wafer component and a pouch component. Accordingly, it is not surprising that McInally does not teach or suggest the present invention, as claimed.

McInally discusses the pressure sensitive adhesive of Cilento, et al. This reference (Cilento, et al.) is also concerned with an adhesive to seal the appliance to a patient’s body. Cilento does not teach or suggest the two-component adhesive interface, as presently claimed in claim 1. There is no teaching or suggestion of adhesion and separation of a two component ostomy device with a pressure sensitive adhesive, as claimed in amended claim 1.

Further verification that McInally is directed to a stoma seal can be found in column 8, lines 40-48. McInally is clearly discussing sealing between the skin and an attaching component of the ostomy device and not the present invention, as claimed.

The reference Wagner alone or in combination with McInally does not anticipate or render obvious the present invention, as claimed in amended claim 1.

Wagner does not teach or suggest a pressure sensitive adhesive interface between a body attaching wafer component and a pouch component, as claimed in amended claim 1. Wagner is directed to a liquid distribution system for spreading liquid from the stoma around the skin barrier thereby seeking to prolong the life of the barrier seal.

The Examiner indicates that Wagner discloses a two component ostomy faceplate and coupling system comprising a body attaching blotter ring/adhesive coated interface 25 that adheres to the circumference of the wearer’s stoma 5 (column 4, lines

50-53 and column 5, lines 9-13) and a pouch component (Fig. 1). The adhesive component 25 is replaceable/removable (column 4, line 67 to column 5, line 3) and positioned around the stoma to collect stomal fluid (Figs. 3, 4). The adhesive interface 25 includes polydimethylsiloxane (column 7, lines 62 to column 8, line 7) for body conformation (column 5, lines 13-21) and resistance to stomal fluid migration (column 8, lines 30-35).

The Examiner indicates that the adhesive interface 25 of Wagner includes polymethylsiloxane for body conformation and stomal fluid migration.

The adhesive interface of Wager does not teach or suggest the adhesive interface of the present invention, as claimed in amended claim 1.

The so-called adhesive interface of Wagner is part of the blotter ring. This ring is described in column 4, line 62 to column 5, line 3 as being capable of being fixed to the silicone support washer with silicone which may be silicone glue, or the blotter ring may be molded into the support washer during manufacture of the washer. The blotter ring may also be supplied as a replaceable structure, with blotter material fixed to a ring which snaps into a groove on the support membrane.

As presently claimed in claim 1, the adhesive interface of the present invention is pressure sensitive. The adhesive interface is located where the body attaching wafer component and the pouch component adhere to each other and are separated from each other. The adhesive interface of the present invention as claimed is also resealable and resistant to the migration of stomal effluent into the adhesive interface.

The blotter ring of Wagner does not teach or suggest the presently claimed interface in which the wafer is adhereable to and is separatable from the pouch while being resealable and resistant to migration of stomal effluent.

Wagner describes the blotter ring 25 as made from a porous material such as cloth, sponge, non-woven mat or other absorbent or wicking material which can distribute absorbed liquid uniformly over the circumference of the blotter ring (column 8, lines 55-59). This system is directed to a redistribution of stomal effluent and not an adhesive interface resistant to migration of stomal fluids into the adhesive interface. Wagner teaches a device that encourages migration of liquid.

Wagner does not teach or suggest an adhesive interface that resists migration of stomal effluent and it does not teach a body attaching component and a pouch component having an adhesive interface where the two-components are adhereable to each other or separatable from each other as presently claimed in claim 1.

Abber teaches silicone based adhesives and is cited by the Examiner for its teaching of the disclosed adhesive use in a transdermal therapeutic device.

The two-component ostomy device having the adhesive interface, as presently claimed in claim 1, is not taught or suggested by Abber. Accordingly, Abber applied alone or in combination with McInally and/or Wagner does not render the present invention anticipated or obvious.

Allowance of this application is respectfully requested

Respectfully submitted,

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Date: October 17, 2006

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